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MANAGING DIRECTOR

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The Hon Fran Bailey, MP
Chair
House of Representatives
Standing Committee on Primary Industries and Regional Services
Parliament House
CANBERRA ACT 2600

Dear Ms Bailey

Primary Producer Access to Gene Technology

Grain production is widely acknowledged to be one of Australia's most efficient industries. In the past five years the grains industry has made a significant contribution to the national economy, its annual gross value of production increasing to some $6 billion. Importantly, this output matched the quality specifications of discerning customers.

If the industry is to continue to be successful it is essential that grain production remains profitable. This will depend on the industry's ability to adapt to changing markets at home and overseas, the availability of new varieties and the continued development of cost-efficient production systems. A profitable grains industry is also the key to the sustainable use of natural resources.

Biotechnologies, including gene transfer technologies, have the potential to improve the profitability of grain producers over the next ten years, and beyond. To capture the full benefit of these technologies the industry is aware of the need to address consumer attitudes to genetically transformed products and understand the increasingly complex intellectual property and environmental issues attached to gene technologies, at a national and global level.

For these reasons the GRDC is pleased to participate in the Standing Committee's inquiry into Primary Producer Access to Gene Technology. If further information is required by the Committee in respect of any of the issues raised in the GRDC's submission, I shall be happy to respond.

Yours sincerely

JOHN LOVETT
Managing Director

The Grains Research and Development Corporation

The Grains R&D Corporation (GRDC) is a statutory corporation funded by a levy on graingrowers which is matched by the Commonwealth Government. There are, at present, 25 leviable crops spanning temperate and tropical cereals, oilseeds and pulses.[1] The GRDC has a mandate to plan, develop and oversee its research and development (R&D) investment in the $6 billion industry which embraces these crops. Its charter is to invest the funding contributions of grain producers and government in grains industry research. This is achieved through:

- agreement by grain producers to levy their output in order to provide funds for research into industry issues, and
- agreement by the Commonwealth Government to match half of the research expenditure up to a maximum of 0.5 per cent of the gross value of production (GVP), provided the Commonwealth contribution does not exceed grower levies.

The GRDC derives its objects, functions and powers from the *Primary Industries and Energy Research and Development (PIERD) Act* 1989. This enabling legislation provides the foundation for the GRDC's accountability to the Commonwealth Parliament, the Minister for Agriculture, Fisheries and Forestry and the Australian grains industry for securing the greatest possible returns from the research in which it invests.

The objects of a group of R&D Corporations, including the GRDC, are set out in section 3 of the *PIERD Act* and are to make provision for the funding and administration of R&D with a view to:

- increasing the economic, environmental or social benefits to members of primary industries and to the community in general by improving the production, processing, storage, transport or marketing of the products of primary industries;
- achieving the sustainable use and sustainable management of natural resources;
- making more effective use of the resources and skills of the community in general and the scientific community in particular, and
- improving the accountability for expenditure upon R&D activities in relation to primary industries.

The GRDC does not undertake research itself. The Corporation's planning and investment framework links grains industry and government objectives with research strategies designed to improve the industry's performance. Within this strategic planning framework, the Corporation identifies stakeholder requirements, specifies R&D outputs for programs and projects and enters into contracts with research providers to deliver these outputs.

The ultimate return from the GRDC's investment in research and development should be enhanced profitability of grain farm businesses. Future profitability will depend on the industry's continuing ability to adapt to changing market signals, the availability of new crop varieties and the ongoing development of farming systems to improve cost-efficiency and make better use of the natural

[1] Wheat
Coarse Grains : barley, oats, sorghum, maize, triticale, millets / panicums, cereal rye, canary seed
Pulses : lupins, field peas, chickpeas, faba beans, vetch, peanuts, mung beans, navy beans, pigeon peas, cowpeas, lentils
Oilseeds : canola, sunflower, soybean, safflower, linseed

resource base. To improve the profitability of grain producers, the GRDC has set itself four Investment Objectives for the period 1997 to 2002:

IO1. Meeting Quality Requirements;
IO2. Increasing Productivity;
IO3. Protecting and Enhancing the Environment, and
IO4. Delivering Outcomes.

GRDC Investment Objective One: Meeting Quality Requirements

The programs within this objective are key elements to adding value to Australia's grain harvest. The GRDC's investment in IO1 in 1999-2000 is budgeted at $29 million or approximately 28 per cent of its annual expenditure budget, with a focus on:

- improving measurements of quality that are used to define and/or predict the processing characteristics of wheat for different end uses;
- tailoring wheat and barley varieties to the increasingly precise needs of discriminating buyers with a research focus on instant noodles for the Asian market and malting barley for Japanese brewers;
- defining the quality parameters for pulses and oilseeds, and
- grain storage, treatment and harvest strategies to meet market demand and safety requirements.

GRDC Investment Objective Two: Increasing Productivity

The theme of this Investment Objective is increasing the production of Australian grains. Technologies and intellectual property developed by research programs within IO2 may be applied to other research areas, including those in IO1. The GRDC's investment in IO2 in 1999-2000 is budgeted at $27 million or approximately 26 per cent of its annual expenditure budget, with a focus on:

- providing new sources of genes for quality, disease resistance or other traits to plant breeders through genetic engineering;
- delivering high yielding, profitable grain varieties that are well adapted to a range of soil types, environments and farming systems, and
- cost-effective disease, weeds and pest management programs.

GRDC Investment Objective Three: Protecting and Enhancing the Environment

The theme of this Investment Objective is maintaining and increasing the value of Australia's natural resources. The GRDC's investment in IO3 in 1999-2000 is budgeted at $24 million or approximately 23 per cent of its annual expenditure budget, with a focus on:

- farming systems which utilise water more efficiently in order to reduce dryland salinisation and soil acidification;
- higher performance pasture cultivars to reduce groundwater recharge, and

- improving the chemical and biological fertility of soil by building organic matter.

GRDC Investment Objective Four: Delivering Outcomes

This Investment Objective was designed to improve the extension of research results with a view to improving the skills base of farmers, scientists and others in the grains industry. The GRDC's investment in IO4 in 1999-2000 is budgeted at $4.6 million or approximately 4 per cent of its annual expenditure budget, with a focus on:

- packaging information from the outputs of GRDC initiated research, while assuring its target audience, and
- developing delivery networks in a way that best satisfies the needs of the GRDC's target audiences.

GRDC responses to the Inquiry Questions

1. The future value and importance of genetically modified varieties

1.1 The Australian grains industry is a major exporter

By world standards, Australia is a relatively small producer of grain, with the major cereals, wheat and barley, accounting for around 3 percent and 2 percent respectively of annual world production. The Australian grains industry is, however, a major exporter. Around 80 percent of its wheat, for example, is sold on international markets. This results in Australia accounting for 15 percent of world wheat trade, making it the fourth largest exporter after the United States, Canada and the European Community. Australia also exports coarse grains, pulses and oilseeds.

Through the generation of export earnings the grains industry makes a significant contribution to the welfare of the Australian economy. In 1997-98, for example, the industry provided $5.1 billion in export earnings representing approximately one-quarter of total farm exports.

A key to the industry's success in achieving increased efficiency and remaining competitive has been its uptake of new technology to increase yield and reduce costs. This has been made possible by the continuous introduction of new and improved cultivars and better on-farm management practices. The conventional method used by the research community to develop these new cultivars has been plant breeding.

1.2 Conventional Plant Breeding

Plant breeding is a process of creating diversity by crossing and/or backcrossing parental lines and selecting for the characteristics sought from within the diversity of the resulting crossbred lines. These lines segregate genetically for a number of generations so that selection is difficult in early generations, and can usually only be done for major characteristics. After 5 or 6 generations of self-fertilisation, the lines are substantially 'fixed', and hence selection can be more rigorous.

Nevertheless, breeders select for as many of the characteristics they are seeking as they can in early generations, as it becomes increasingly more expensive to test for characteristics such as yield across

environments and years in later generations. Factors such as plant morphology, maturity, resistance to a number of diseases, and some quality characteristics can be selected for in early generations. As soon as possible, a breeder will start to select for yield and major quality characteristics.

Usually by the 5th or 6th generation, a breeder is reasonably confident of the material, and is ready to test more widely for yield. Plant breeders may continue to undertake this testing themselves, but in many breeding organisations, the material is then handed over to a variety testing unit which conducts the intermediate and advanced yield trials across a State or region. Encouraged by the GRDC, advanced lines are increasingly being exchanged between testing units, and between the public and private sectors. This conventional process of producing a new grain cultivar may take up to thirteen years.

1.3 Gene Technology

Gene technology is the deliberate addition, alteration or removal of small amounts of genetic material in order to change the characteristics of an organism. In order to improve plants using gene technology, it is necessary to first identify individual genes that confer a required trait from within the thousands of other genes that comprise the donor organism. Scientists have developed several ways of determining which genes control specific characteristics. For production and marketing purposes these characteristics can be divided into:

- quality traits e.g.
  - protein quality
  - oil quality
  - reduced anti-nutritional factors.
- crop production traits e.g.
  - herbicide resistance
  - insect resistance
  - disease resistance
  - stress tolerance.

After identifying the gene that determines the desired characteristic a number of techniques are used to separate the gene from the source DNA (deoxyribonucleic acid) and insert it into the recipient plant. Once modified plants that express the desired new characteristics have been obtained they then undergo further breeding and evaluation, usually over three or more years, to develop plant varieties with suitable agronomic performance.

Gene technology, therefore, is not an alternative to conventional plant breeding, but an additional method that enables breeders to effect precise genetic changes many of which are not possible through conventional breeding procedures. By reducing the time required to develop a new cultivar gene technology also has the potential to improve the efficiency of conventional plant breeding programs.

1.4 Examples of gene technology within the GRDC's portfolio

In April 1999, the GRDC entered into a strategic alliance with the AWB Limited and CSIRO Plant Industry to generate innovative intellectual property and new generation plant biotechnology capability for the Australian grains industry. This Graingene partnership represents a framework for research and industry groups to work together to bring discoveries successfully to fruition. Australian and international research organisations and companies will be invited to become Graingene 'associates' - to participate in this alliance, through involvement in individual research projects. The research fields include:

- genomics;
- new breeding and product specification technologies;

- yield increase and performance traits;
- resistance to pests and diseases;
- crop nutrition and abiotic stress, and
- product quality.

The GRDC is also investing in biotechnology research across its existing portfolio of cereal, oilseed and pulse projects. In cereals the focus is on:

- improving the efficiency of transformation for cereals, including wheat, barley, and sorghum;
- identification and insertion of novel genes for quality, disease resistance, and other traits;
- new techniques for improving the efficiency of molecular markers in plant breeding;
- reproductive biology of crop plants including hybrid plants.

Oilseed crops are at the forefront of application of gene technology in Australia. The reasons for this include:

- the ease of transformation of these crops;
- the close relationship of the genetic information in many oilseed crops to the developments in gene technology pioneered in the experimental plant *Arabidopsis*;
- economically important oil quality characteristics are well understood biochemically and genetically, with most of the key genes having been already cloned.

The principal benefits expected by the oilseeds industry arising from GRDC supported research are reduced agrochemical usage, new markets for new products, healthier fats and oils, and renewable sources of industrial oils.

With GRDC support gene transfer systems have been developed for a number of pulse crops including narrow leafed and yellow lupins, chickpeas, and peas. Similar systems are being developed for lentils, faba beans, and white lupins. The modified traits will enhance the drive to produce consistent, high quality products to meet market requirements.

2. The ability of producers to compete using traditionally available varieties

Three significant trends in the global environment will continue to have implications for the Australian grains industry over the next decade:

- the increasing demand for high quality food;
- the increasingly competitive international commodity and product markets, and
- the focus on environmental management.

2.1 The increasing demand for high quality food

Eighty percent of Australia's grain production is sold on international markets. Competition for these markets is intense. Increasingly, large international food companies are placing considerable value on quality characteristics required to produce end products to satisfy the very precise needs of their customers. Access to markets, both abroad and domestically, will depend on meeting strict quality criteria, both from the viewpoint of functional properties of grains and acceptable levels of contaminants.

To remain competitive, the Australian grains industry will need to invest, extensively, in technologies that allow these market specifications to be met. Biotechnology, through its ability to improve product quality, will provide the industry with the ability to meet the market specifications of increasingly discerning customers and to maintain Australia's 15 percent share of the global grain market.

2.2 The increasingly competitive international commodity and product markets

Grain production is now widely acknowledged to be one of Australia's most efficient industries. This is attributable to a sustained growth in productivity since 1977. Over the period 1977 to 1997, average annual productivity growth is estimated to have been 3.7 per cent on crop specialist farms and 2.6 per cent on mixed crops-livestock farms[2].

To maintain or increase its international competitiveness, the Australian grains industry must continue to achieve productivity increases equal to or better than its rival exporters. Australia's competitors in international markets are committed to the increased application of gene technology to achieve competitive advantage through increased yields and reduced costs. Australia's contribution to the worlds grain trade is significant and the industry will need to utilise gene technology to remain competitive.

2.3 The focus on environmental management

Farm practices that are not sustainable at farm level can deleteriously affect the wider environment, whether this be at catchment, regional or national level. The community, nationally and internationally, is becoming increasingly aware of the environmental issues associated with agricultural production.

Developments in grains industry farming systems research over the past few years - refinement of reduced tillage systems and stubble retention techniques, rotational cropping, herbicide technology and disease control strategies - have provided the industry with the skills to manage the on-farm resource base more competently than a decade ago. The environmental benefits arising from biotechnology could build on this trend and include:

- the reduced use of farm inputs such as:
  - pesticides (through the development of pest resistant varieties);
  - chemical fertilisers (through improved nutrient efficiency), and
  - irrigation.

- more efficient use of the agricultural resource base through:
  - better use of soil and plant nutrients, and
  - bio-remediation of degraded areas.

3. The commercialisation and marketing of agricultural and livestock production varieties

The GRDC's policy on the commercial release of publicly bred cultivars is as follows.

> *'The GRDC's first objective is to optimise economic benefits to the grains industry and the nation, as a whole. It does not seek, in the first instance, to maximise the immediate financial*

[2] ABARE, Australian Commodities1/1999.

returns to itself from commercialisation. New cultivars should therefore be made available to growers as soon as is practicable, after merit is established, to ensure appropriate transfer of technology. New cultivars are generally developed by consortia of funding organisations which license the outcome for release by commercial organisations. Appropriate returns are required by these various participants, commensurate with the risks involved and the need to encourage on-going innovation.'

The rationale for this approach is that the GRDC invests in plant breeding on behalf of two stakeholders, namely, grain growers and the Commonwealth Government. It, therefore, has a concern and obligation to ensure that the outcome of its investments, *inter alia*, being new cultivars, is made available to growers for the benefit of the industry and the nation.

The GRDC seeks to ensure that, where it has invested in the development of new cultivars, these are made available to growers and the industry without unnecessary delays. Thus, adopters of such new technology can obtain maximum benefits once the advantages of new cultivars are proven.

The GRDC is, however, frequently only one of a number of organisations investing in the development of new cultivars, which is often undertaken jointly by the Corporation, and other publicly / privately funded agencies (such as State Departments of Agriculture). In such instances, the GRDC will have an influence over the terms on which cultivars are released but cannot determine these in isolation from the interests of the other parties.

The commercialisation of the outputs of investment in plant breeding, in public / privately funded consortia, usually involves the transfer of research and know-how to commercial entities, such as seed companies, on pre-determined terms and conditions. In turn, these companies make cultivars available to growers. In general, the commercialising entity (usually the seed company) will pay a royalty to the development consortium for the use of the technology and will make the new cultivar available to growers on terms which provide it with adequate commercial return. It is recognised that an inadequate return to the commercial participant will inhibit innovation and, thereby, reduce benefits to the industry at large.

An appropriate balance, therefore, is struck between these considerations in the GRDC's implementation of its policy for the commercialisation of new cultivars.

4. The cost to producers of new varieties

Grain producers face declining terms of trade for their product, a trend which has endured for half a century. The GRDC recognises the essential requirement to invest in research that assists farmers to maintain profits and allows restructuring to occur to maintain thriving farm businesses. The Corporation addresses the declining terms of trade through the introduction of improved cultivars, production methods and farming systems that reduce the cost of farm inputs and increase productivity and profit margins.

Australian grain producers bear significant monetary costs to produce grain, with average operating costs being 64 percent of annual income. Typical costs include seed, operating costs for spraying, land preparation and harvesting, plus the cost of inputs including fertiliser, fungicides, herbicides and insecticides.

The gross margins of Australian grain producers vary depending upon agro-ecological zone but, on average, farm input costs account for 30 to 40 percent of revenue per hectare in wheat crops. In relation to total costs, seed costs are relatively low at $22/ha, whilst farm chemicals account for $70/ha and operating costs average $34/ha.

As well as increasing yield and improving the quality of the end product, gene technology offers the capability to substantially reduce the cost of farm inputs. Through the development of pest resistant cultivars, and cultivars with improved tolerance to herbicides, the costs of application of these chemicals can be reduced. Given that Australian grain producers spend approximately $750 million annually on chemical sprays, the availability of cultivars that reduce the frequency and level of these inputs is more significant than the cost of the seed required to plant a new variety.

5. Other impediments to the utilisation of new varieties by small producers

Biotechnology and other new technologies have made major contributions to plant science in the last decade. The advances are now beginning to reach into commercial agriculture, with an expected rapid increase in the growth of commercial, transgenic crops, differentiated from other crops by significantly higher levels of quality and yield and greater efficiencies in production. Improved human nutrition and health attributes in the new crops will increase market opportunities.

However, large multinationals, previously based in agrochemicals, have increasingly oriented their business systems to gene technologies, with strategic mergers and acquisitions putting them in strong Intellectual Property (IP) positions in relation to key gene and transformation technologies.

The vertical paths into agricultural production of these multinationals are becoming increasingly important in international markets. Their powerful IP positions are beginning to impact on the Australian situation, potentially limiting the operation of Australian research providers. Although Australia has excellent plant gene technology research, it accounts for only around 2 percent of world activity.

Unless Australia can gain entry to global agribusiness systems via strategic alliances with multinationals and/or develop a stronger national capability and alternative technologies, it runs the risk of becoming relegated to being a marginal, dependent player in this key research field.

To avoid being marginalised in this new agricultural revolution, the GRDC, the AWB Limited and CSIRO Plant Industry entered into a joint venture in April 1999 to strategically position Australia in the global grain business of the 21st century. The Graingene partnership will concentrate on the development of novel and valuable technologies in the areas of genomics, new breeding and product specification technologies, yield increase and performance traits, resistance top pests and diseases, crop nutrition and abiotic stress, and product quality.

Amongst the anticipated outcomes are:

- strong linkages between plant breeding and advances in biotechnology for the development of transgenic cultivars with superior quality and yield and other differentiating features;
- strong negotiating ‘coin’ and a more powerful intellectual property position, and
- improved access to key technologies and a wider range of international marketing opportunities.

6. Assistance to small producers to develop new varieties and the protection of the rights of independent breeders, in relation to genetically modified organisms

6.1 R&D Corporation (RDC) Model

An historical feature of agricultural research in Australia is the partnership between Government and industry. In the rural sector, Australia is unique in that primary producers in the chicken meat, cotton, dairy, deer, dried fruits, egg, fishing, forest, goat fibre, grains, grape and wine, honeybee, horticultural, meat, pasture seed, pig, rice, sugar, tobacco and wool industries participate directly in financing their own research. In the case of the grains industry, the instrument used to achieve this is:

- agreement by grain producers to levy their output in order to provide funds for research into industry issues, and

- agreement by the Commonwealth Government to match half of the research expenditure up to a maximum of 0.5 per cent of the gross value of production (GVP), provided the Commonwealth contribution does not exceed grower levies.

Government matching of industry contributions to the GRDCs reflects:

- the high risk and uncertain nature of research,

- potentially large external benefits to the community, and

- the difficulty faced by small producers in appropriating the full commercial return from research when others can benefit without paying - the 'free rider' problem.

These issues are particularly acute in agriculture where the production sector is dominated by many small businesses which, alone, cannot fund the scale of the R&D necessary to maintain their industry's competitiveness in world markets. In the absence of government support it is likely that these instances of market failure, common to many areas of research endeavour, would lead to under-investment in research from the community's viewpoint.

Another major policy response to under-investment in research activity has been for governments to improve the rewards for undertaking research by assigning ownership rights over 'new knowledge'. Patents and plant variety rights fall into this category. This issue is discussed further in Section 7: 'The appropriateness of current variety protection rights, administrative arrangements and legislation, in relation to genetically modified organisms'.

6.2 The GRDC's Government / Industry Operating Environment

The GRDC invests grain grower and Commonwealth Government funds in R&D to deliver benefits in the future. Its portfolio is supported by levies on twenty-five grain commodities, ranges in scope across national, regional and local initiatives, and requires choices among research investments in the industry's primary, processing, or distribution and marketing sectors. Decision-making within the Corporation involves the evaluation of competing research alternatives across this diverse portfolio to secure the best possible overall return to its stakeholders.

'Partners for Profit', the GRDC's Five Year Plan for 1997 to 2002, locates the GRDC in a broad sphere of influence which embraces governments, industry organisations, research providers, other research investors, and the grains industry including, importantly, 50,000 grain growers. The GRDC's structure, adopted in 'Partners for Profit', recognises the complexity of grains R&D and the need to plan, deliver and communicate in all these dimensions. The structure is designed to:

- promote an environment which allows new ideas and innovation to come forward and, where appropriate, the authority to accomplish whatever large-scale actions are essential to meet the GRDC's accountabilities;

- access strategic advice on long term directions in the grains industry;

- realise the GRDC's priorities and evaluate research investments in an efficient and effective manner, consistent with business best practice;

- identify a portfolio of R&D investments that is well balanced in terms of national and regional industry priorities;

- harness variations in local conditions and facilitate the rapid and accurate use of local information to exploit seasonal and geographic differences, and

- develop Programs, as the fundamental building blocks, based on clear industry / community objectives, the actions needed to meet these objectives and the resources required to deliver the R&D outcomes.

The GRDC structure recognises variations in local conditions and provides for advisory Panels covering the northern, southern and western grain growing regions of Australia. The three regions embodied in the Panel divisions correspond with the three prominent grain growing areas in Australia: north, south and west.

The GRDC's three regions reflect market and production realities. Each has distinctive features which warrant focused planning and research management in plant breeding, farming systems, soil, grain storage and handling, product development, market opportunities, and technology marketing. The GRDC's regions also bridge state borders to ensure regional access to multiple research providers and outputs.

A major GRDC achievement is the level of national coordination made possible by the interaction across the GRDC's three Regional Panels. In 1997-98, for example, a wide range of new grain varieties were released for use across Australia - all adapted to specific regions and growing conditions including:

- ten new, market-targeted wheats, including a prime hard bread wheat, a new biscuit wheat, and a range of wheats for noodle production and other specific markets;

- five new malting barleys with improved quality characteristics, and

- a range of rotational crops to benefit soil and to help combat the build-up of crop diseases including four new chickpea varieties, two new field peas, four new lupin varieties, five new high-value lentil varieties, three new soybeans, and eight new canola varieties.

7. The appropriateness of current variety protection rights, administrative arrangements and legislation, in relation to genetically modified organisms

7.1 The Regulatory Environment

Various Commonwealth and State agencies are involved in the regulation of genetically modified organisms and their products in Australia: the Genetic Manipulation Advisory Committee (GMAC), the Australia New Zealand Food Authority (ANZFA), the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) and the Australian Quarantine and Inspection Service (AQIS).

i) Genetic Manipulation Advisory Committee (GMAC)

The Genetic Manipulation Advisory Committee (GMAC) is a non-statutory body which was established to oversee the development and use of novel genetic manipulation techniques in Australia. GMAC has no legislative force. It assess whether such work poses potential hazards to the community and recommends appropriate safety measures for researchers working with GMOs. It also seeks comment on proposals for planned release of GMOs into the environment from members of the public and relevant government agencies. GMAC's advice on these proposals is copied to the relevant Commonwealth regulatory bodies (such as ANZFA for a food, or the NRA for an agricultural chemical), State agriculture and environment departments and local councils in the area of the release.

ii) Australia New Zealand Food Authority (ANZFA)

The regulation of food for sale in Australia is primarily a State and Territory responsibility. Each state has individual food laws that prohibit the sale of food that is injurious to health or which bears labelling which is false and misleading. The Australia New Zealand Food Authority (ANZFA) develops uniform food standards in a cooperative arrangement between all Australian States and Territories and New Zealand. Food standards are, essentially, specific performance standards (e.g. composition, specific labelling, permitted residues in food) which amplify and facilitate enforcement of general food laws).

In addition, ANZFA coordinates food surveillance undertaken by the various enforcement authorities and advises the Commonwealth Government on food matters. In this regard, ANZFA is consulted on the safety and identification of food produced through gene technology and seeks to facilitate a uniform interpretation throughout all jurisdictions in Australia and New Zealand.

iii) National Registration Authority for Agricultural and Veterinary Chemicals (NRA)

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) regulates veterinary drugs and products for agricultural use. Definitions of an agricultural chemical product and a veterinary chemical product in the Agricultural and Veterinary Chemicals Act refer to a substance that is defined as an organism or part of an organism, including a genetically modified organism. Transgenic plants with engineered pest resistance through the introduction of genes for novel pesticidal compounds are regarded as 'biological' pesticides and fall under the regulatory control of the NRA.

Transgenic herbicide resistant plants that do not produce an agrochemical do not fall directly under the NRA's charter. However, herbicide resistant plants influence the use of herbicides and the proposed commercial release of such a transgenic variety would require the NRA to consider extension of approval for use of the herbicide to take into account the crop that was modified.

iv) Australian Quarantine and Inspection Service (AQIS)

The Australian Quarantine and Inspection Service (AQIS) is responsible for ensuring that products imported into Australia do not lead to the establishment of pests and diseases. Under the Quarantine Act, AQIS has no specified responsibilities with regard to GMOs. However, all proposals to import goods are assessed using a pest-risk analysis that considers whether the products may pose a pest or disease risk. In addition to this risk analysis, if a product is identified as being genetically modified,

AQIS advises the importer to contact GMAC and notes that the importer should comply with GMAC requirements.

v) The Office of the Gene Technology Regulator (OGTR)

In the 1999 Budget the Commonwealth Government announced it would establish:

- the Office of the Gene Technology Regulator (OGTR) within the Therapeutics Goods Administration (TGA) in the Health and Aged Care portfolio, and
- Biotechnology Australia as an agency within the Industry, Science and Resources portfolio to develop a comprehensive strategy for the development of biotechnology in Australia.

The OGTR's functions will be to:

- regulate all aspects of the development, production and use of genetically modified organisms and their products, where no other existing regulatory body has responsibility, in accordance with principles agreed and enacted by all jurisdictions;
- work with regulatory bodies to ensure the consistent application of standards and harmonise assessments across all systems of regulation, and
- undertake or commission research in the area of risk assessment.

The regulatory framework for gene technology will draw upon existing legislation for the control of food and chemicals currently administered by ANZFA and the NRA. It will also involve new legislation to regulate GMOs and GMO products that do not fall within the mandate of existing systems. The system of regulation is being considered as a set of related elements covering import of GMOs and their products, research, regulation of GMO products, and related post-release control mechanisms.

The GRDC considers, that in drafting the new legislation for the OGTR, the emphasis should be on a comprehensive regulatory regime rather than filling any gaps in the existing regulatory coverage. The objects of the legislation should instill the planned outcomes of:

- market certainty for industry, and
- assurance of safety for the public and the environment.

Commonwealth and State Government resources provided to implement this initiative should be commensurate with the potential loss to the competitiveness of Australia's agricultural sector.

7.2 Australia's Access to Genetic Material

In developing new varieties Australia has made widespread use of germplasm developed through international agricultural research agencies. Australian agriculture is highly dependent upon access to this exotic germplasm which is sourced globally. Increased competition for valuable genetic material and decreasing government aid for international research agencies may reduce Australia's access to genetic material in the future.

The Australian grains industry for example relies heavily on a number of international and national centres including:

CIMMYT	International Centre for Improvement of Maize and Wheat;
ICARDA	International Centre for Agricultural Research in the Dry Areas;
ICRISAT	International Crops Research Institute for the Semi-Arid Tropics, and
CAAS	Chinese Academy of Agricultural Sciences.

There are currently seven Plant Genetic Resource (PGR) Centres in Australia and one in New Zealand, which form the Australasian network. The seven Australian centres were formally established under a (then) Standing Committee on Agriculture decision whereby the Commonwealth provided some $1.2m in capital, and the host organisations (CSIRO and all State Departments of Agriculture except Tasmania) agreed to provide the operating funding. Some centres were functioning long before the agreement, but its adoption gave them the status of national collections.

The following centres within the Australian network of PGRs contain germplasm of relevance to the Australian agriculture:

- Australian Winter Cereals Collection (Tamworth, NSW);
- Australian Temperate Forage Legume Centre (Perth, WA);
- Australian Tropical Field Crops Centre (Biloela, Qld);
- Australian Tropical Forages Centre (St Lucia, Qld);
- Australian Medicago Centre (Northfield, SA);
- Australian Temperate Field Crops Collection (Horsham, Victoria);
- Indigenous Wild Relatives of Crops (Canberra, ACT).

The responsibilities of the PGR centres are to:

- act as the focus for the importation and passage through quarantine for germplasm of their mandate species;
- provide long-term storage for the germplasm in the collection, and ensure the continued viability of all accessions held;
- provide accessions on demand, with appropriate information, both within Australia and overseas, and
- obtain appropriate accessions which have the potential to be of value to the Australian industry.

The operation of these centres is influenced by the Biodiversity Collection Convention which came into force in 1993. It recognised, for the first time, national sovereignty over genetic resources and provided that access to a country's genetic resources must be on mutually agreed terms and subject to informed consent. The only previous international instrument on genetic resources was the International Undertaking on Plant Genetic Resources which recognised plant genetic resources for food and agriculture as the common heritage of mankind, and provided for free exchange of such material between countries.

The Biodiversity Convention has changed the focus in a way that has the potential to be detrimental to agriculture. The Plant Genetic Commission of the Food and Agriculture Organisation has been working for several years to 'harmonise' the International Undertaking on Plant Genetic Resources with the Biodiversity Convention, but has been unsuccessful to date because of the unrealistic expectations of some third world countries of the value of their genetic resources.

It is likely that the interests and concerns of Australian agriculture are not being given sufficient weight relative to the interest of overseas conservation and indigenous groups in developing the

Australian negotiating position for this international instrument. The current situation in Australia is unsatisfactory from the point of view of the agricultural industries. This issue should be a high priority for the newly announced Biotechnology Australia program to be located in the Department of Industry, Science and Resources. Biotechnology Australia's role is to work closely with other Departments to:

- develop a national strategy for biotechnology;
- develop a public awareness program to provide information about biotechnology and gene technology;
- support training for developers and managers of intellectual property, and
- secure better access to genetic resources and gene collections.

7.3 Patents

A common public policy designed to improve the rewards for undertaking research is to assign ownership rights over 'new knowledge'. Patents and plant variety rights fall into this category.

Patenting provides the legal mechanism for ensuring control of proprietary technology that results from investment in research and development. A patent provides the owner with a monopoly right for the technology in the country of grant for the life of the patent (generally 20 years). In return, the inventor must provide a description of the invention that is sufficient to enable others to work the invention after the patent expires. Patents in gene technology are normally sought in three areas:

- an isolated DNA sequence (if it satisfies the normal requirements of novelty and inventiveness);
- patents may also extend to cover transgenic plants carrying the gene and to the products of those plants, provided they also satisfy the criteria of novelty and inventiveness, and
- the methods to clone and insert genes into plants are able to be patented.

Biotechnology has, therefore, lent itself to ownership of intellectual property in a way new to agriculture. Not only are the biological products of biotechnology able to be owned, but the processes by which they came to be developed are subject to patenting as well.

Legal issues associated with the capture and use of intellectual property are consuming a significant and increasing proportion of the budgets of organisations undertaking biotechnology research. An important element of the process used to determine the research priorities of an organisation is to assess the feasibility of the research. In the context of biotechnology research, this assessment has to include consideration of access to and costs of any prerequisite intellectual property required for the research. Research priorities can shift dramatically in light of this assessment. Investigation of legal issues associated with intellectual property requires specialist skills that are not readily available in Australia.

Strategies for the protection of Australian intellectual property in the area of gene technology, and for the capture of benefits in Australia, require greater consideration. Biotechnology Australia should embrace these issues.

8. Opportunities to educate the community of the benefits of gene technology

Worldwide, public acceptance of biotechnology has been mixed. There is strong potential for the public to accept genetically engineered products which are fundamentally similar to those that could be created, although far more slowly, through traditional breeding technologies.

The GRDC has assisted in providing information to the community regarding gene technology and its affect from paddock to plate, with actions including

- involvement in the organisation of the First Australian Consensus Conference on 'Gene Technology in the Food Chain';
- becoming a founding member of the Agrifood Alliance Australia (AAA)
  - an alliance formed to provide more information to the general community following the consensus conference;
- initiation of an Australian Research Council / R&D Corporation strategic workshop on 'Genomics and Gene Technology', and
- representation on the Ministerial Biotechnology Consultative Group (BIOCOG).

The GRDC acknowledges that consumer issues should be addressed through coordinated information campaigns to build awareness, public confidence and facilitate informed consumer debate. Communication of accurate, balanced and easy to understand information is an area which is to be addressed by Biotechnology Australia. There is anecdotal evidence that consumers reject the notion that they need to be 'educated' but are receptive to well-presented information and welcome enhanced awareness. The GRDC, as a member of the AAA, has a strong preference to employ the latter terms.

An amount of $2 million has been earmarked from the Commonwealth Government's 1999-2000 budget allocation of $17.5 million to provide public information. Additional funds from industry organisations will also be available to assist this process. (In comparison Canada has an information and public awareness budget in excess of 5 million dollars for the coming year[3].). Lessons learnt during the Consensus Conference may assist Biotechnology Australia in formulating an approach:

- openly discuss with the public the issue of labeling biotech products;
- promote discussion with popular media, on issues around food biotech;
- demonstrate the environmental benefits that biotechnology provides, such as reduced pesticides and less fertilisers;
- promote the merit of a new regulatory regime to the public, and
- encourage the research community to bring value added crops to the market place quickly, enabling health and nutritional value for consumers.

The uncertainty associated with the marketability of genetically modified organisms has been a significant barrier to investment in research and development. Increasing consumer confidence in the safety of genetically modified organisms is necessary to encourage investment in research and to ensure the application of gene technology in Australian agriculture.

[3] McCann Peter, AgBiotech Bulletin May 1999 Canada